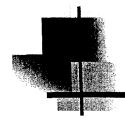
Consumers and OTCs



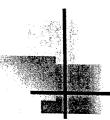
FDA OTC Part 15 Hearing
June 28, 2000
National Consumers League
Linda Golodner and Brett Kay

JUN 2 2000



NCL: Process Issues

- Consumers and responsibility for own health decisions
- 2. 21st Century health information
- 3. Are consumers using OTCs appropriately?
- 4. What OTCs do consumers want?
- 5. What about statins and CVC?
- 6. Consumer/patient information: whose responsibility?



OTC Drugs Study

- Commissioned Yankelovich Partners,
 Inc.
- 1,010 telephone interviews (margin of error plus or minus 3.1%.
- Respondents at least 18 years old
- Interviews May 15 to May 31, 2000



Compared to 5 years ago, making decisions on own

More healthcare decisions on own 58%

■ The same – 31%

■ Making fewer – 9%

First thing you do when facing a minor health ailment

- Rely only on self 53%
- Doctor and yourself 22%
- Rely only on doctor 10%
- Rely on pharmacist and yourself 7%
- Rely only on pharmacist 3%



When treat self, preferred treatment

- An OTC 57%
- Cure myself naturally 21%
- Dietary supplement 16%
- Never self treat 2%



Resources to help decide which OTC to take

- Information on the label 66%
- Doctor 63%
- Friends and relatives 58%
- Pharmacist 52%
- Information on news or article 38%
- Nurse 34%
- Advertisements or promotions 29%
- Internet 10%

How often do you generally read the labels on OTCs?



- Most of the time 17%
- Sometimes 10%
- Rarely 4%
- Never 3%

How easy are the labels of OTCs to read and understand?

- Very easy 44%
- Somewhat easy 31%
- Neither easy nor difficult 8%
- Somewhat difficult 12%
- Very difficult 5%



How often do you read information inside the package?

- Always or nearly every time 37%
- Most of the time 21%
- Sometimes 19%
- Rarely 10%
- Never 12%

Taken more than recommended dose



- Most of the time 6%
- Sometimes 18%
- Rarely 15%
- Never 53%





- Most of the time 5%
- Sometimes 13%
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How satisfied are you with the range of medications OTC?

- Extremely 12%
- Very 39%
- Somewhat 41%
- Not very 3%
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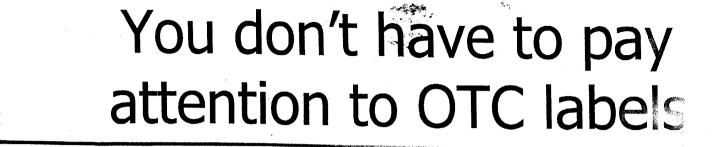


OTCs are safer than prescription medications

■ Agree – 25%

■ 18 – 34 agree – 29%

■ Disagree – 65%



■ Agree – 10%

■ Disagree – 89%



No problems with OTC interacting with Rx medications

■ Agree – 16%

■ Disagree – 78%



Wish some of my prescription medications were OTC

■ Agree – 65%

■ Disagree – 29%



Methodology

- Commissioned Opinion Research Corporation International
- Random Digit Dial
- Sample N=1,007 (margin of error plus or minus 3.1%)
- Interviews June 7 to June 18, 2000
 - Age 35+
 - "Very/Somewhat Concerned About Their Cholesterol Level."



Survey Topics

- Sample Description
- Disease Prevention
 - Activities
 - Information
- Attitudes
 - Treatment (General)
 - Cholesterol Treatment
 - OTC Cholesterol Treatment
 - Good Idea?
 - Use

Sample Description Demographics

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Gender	(%	Female)
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Total Interest/Non-Interest 52/60

41

38/41

59

58/63

50

51/48

Sample Description-Psychographics (%)

 Know Current Cholesterol Levels 	49	48/50
■ Believe Their Cholesterol Level High	41	13/30
 Believe Their Health Risk High 	29	35/19
 Visit Doctor Within Last year 	81	82/79
 Have Health Insurance 	91	90/92
 Have RX Drug Coverage 	89	87/91

Disease Prevention Activities (%) (Regularly/Often)

Exercise	73	70/77*
Visit the Doctor	67	67/66
Take vitamins	65	69/59*
Take Rx Drugs	56	57/52
 Take ASA to Prevent Heart Attack 	32	34/29
Take OTC Drugs	32	34/27*
Take Garlic, Fish Oil,	28	30/26
Other such Supplements		

Disease Prevention Information (Regularly/Often) (%)

Nutrition labels	69	68/69
Doctor	65	65/64
Drug Labels	61	63/57
Magazine Articles	47	49/44
Newspaper	43	46/38*
Pharmacist	38	38/38
TV Commercials	35	39/28*
Internet	23	23/23

General Attitudes Re: Treatment (strongly/Somewhat Agree) (%)

Doctor Knows Best	85	86/83
Rx Drugs Cause Too	61	62/59
Many Side Effects		
Don't Like to Take Rx Drugs	60	59/63
 More Comfortable Taking OTC 	39	43/35*
Than Rx Drugs		
OTC Safer than Rx	28	32/23*
OTC More Costly than Rx	26	27/24
 OTC More Effective than Rx 	21	23/18

Cholesterol Treatment Attitudes (%) Strongly/Somewhat Agree

Barrens American Company		
 Reducing Cholesterol will 	92	94/89*
Add years to my life		
High Cholesterol is a serious	89	90/87
threat to your health		
 Often seek advice of doctor 	75	78/70 *
Doctor gives advice/I make	69	69/70
own decision		
Find information about	51	56/44*
cholesterol confusing		
Frustrated by how hard it is	34	41/22*
to control cholesterol		-
Cholesterol is high, I want to treat	17	19/14
 Nothing I can do to control my cholesterol 	7	7/6
· · · · · · · · · · · · · · · · · · ·		

Low Dose Nonprescription Cholesterol Treatment (%)

Good Idea

65

82/41*

■ Bad Idea

29

14/53*

Don't Know

6

4/6



 Good Idea Expense Readily Available Helps Lower cholesterol Don't have to see doctor 	65 30 22 20 13 (n=83)	82/41* 32/22* 24/20 21/18 21/18
 Bad Idea Need to consult doctor Don't know how to take Too easily available/abuse 	29 44 (n=128) 20 16	14/53* 49/42 27/16 19/14

If OTC Cholesterol Drug Available (%) Strongly/Somewhat Agree

Still talk to Doctor	91	94/88*
 Really help manage cholesterol w/o taking Rx meds 	84	91/75*
 Ask Pharmacist questions 	83	88/76*
 Not have to watch what I eat 	15	18/12*
 Not See Doctor 	11	10/13*
 Would not have cholesterol checked 	9	10/7
 Take Double Dose 	6	6/6



If Directed on Label to See Doctor Prior to Use (%) Very/Somewhat Likely

 Use only if Doctor said it was O.K. 	87	93/80*
 Consult Doctor before use 	86	89/82*
 Use only if I understood label 	78	90/60*
 Use it and stop having check-ups with doctor 	16	19/11*

Use Instead of Garlic, Fish Oil, Other Such Products

Definitely

12

18/3*

Probably

39

55/15*

Probably Not

26

15/42*

Definitely Not

15

4/34*

Confident I Can Use it Correctly (%)

Very Confident	42	52/27*
Somewhat confident	34	40/24*
Not Too Confident	11	6/20*
Not At All Confident	11	1/26*



Conclusions

(Among Population Concerned About Cholesterol)

- Already Taking Some Actions
- Solid Belief in Consultation/Visitation to Doctor
- OTC Low-dose Cholesterol Medicine is a Good Idea (2-1 margin)
 - Consumers will still talk to Doctor
 - Consumers will consult with Pharmacists
 - Few will avoid cholesterol checks/Dr. visits
 - Half Population will use in place of supplements
 - Most consumers feel confident they can use OTC cholesterol medicine correctly



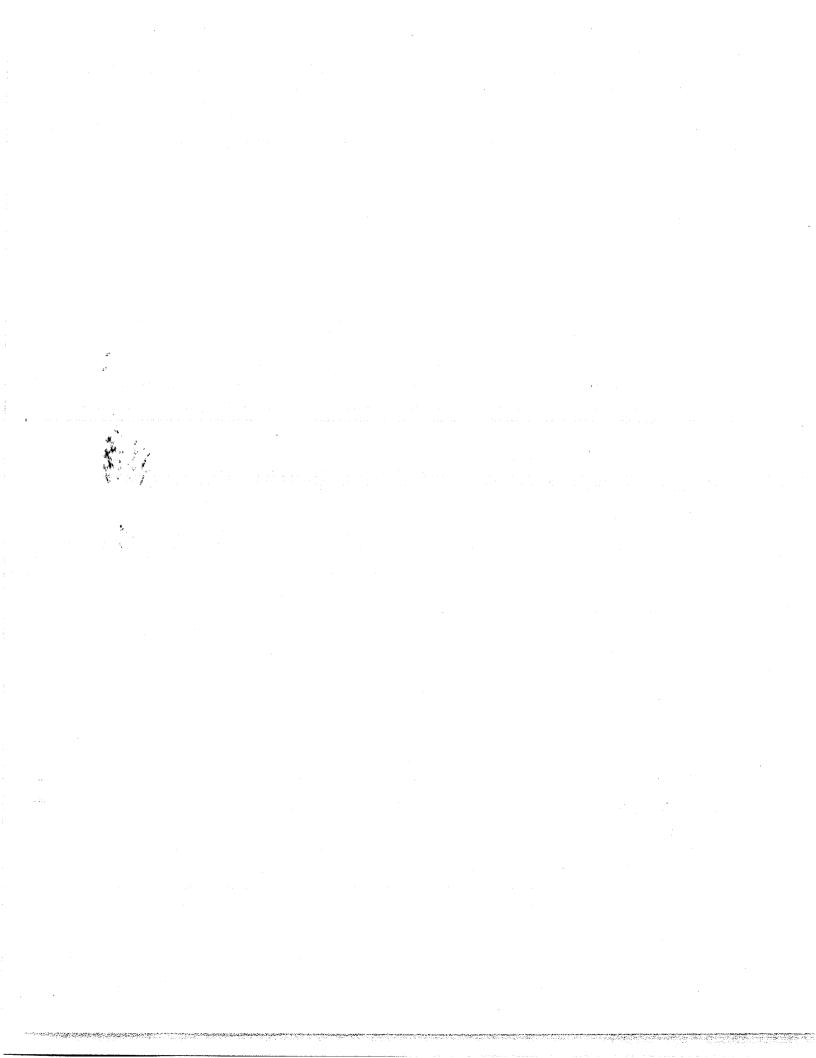
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- Label Readability—Easy to Read and Understand
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 - State clearly on the label
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Recommendations (continued)

- Important to have regular cholesterol tests and to know the numbers
- Know the Warnings, Precautions, Side Effects
 - State clearly on label
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 - Drug-Drug
 - Food-Drug
 - Dietary Supplement-Drug
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9

JUN 200



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FDA OTC Part 15 Hearing June 28, 2000 National Consumers League Linda Golodner and Brett Kay



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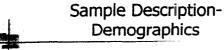
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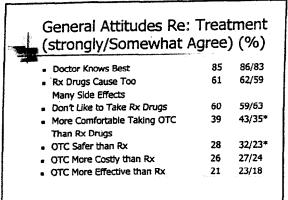


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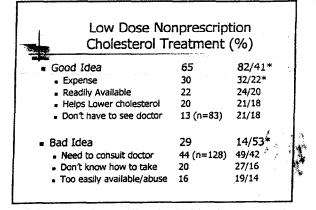
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